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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,590	07/12/1999	BJARNE DUE LARSEN	55508 (45487)	5316
21874	7590	05/19/2005	EXAMINER	
EDWARDS & ANGELL, LLP			LUKTON, DAVID	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1653

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/341,590

Applicant(s)

LARSEN, BJARNE DUE

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 83,87,88,90,101 and 102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83,87,90,101 and 102 is/are rejected.
- 7) ☒ Claim(s) 88 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/4/05 has been entered.



Claims 83, 87, 88, 90, 101 and 102 are now pending. Claims 83, 87, 88, 90, 101 and 102 are rejected in this Office action; claim 88 is objected to because of its dependence on a rejected claim.



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 83 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 83 is drawn to a peptide conjugate comprising X and Z, wherein "Z" is (Lys)<sub>4-10</sub>, and "X" is any of several possibilities. One of those possibilities for X is SEQ ID NO: 98, which is the second to last entry in the claim. The

issue is not that support is lacking for SEQ ID NO: 98; rather, the issue is whether support exists for any of the following:

YGGFLKEEEEKKKKK

YGGFLKEEEEKKKKKKK

YGGFLKEEEEKKKKKKKKK

YGGFLKEEEEKKKKKKKKKKK

It does not appear that support exists for any of the foregoing. Applicants are requested to point to the relevant page and line number.



Claims 83, 87, 90, 101 and 102 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 87, integers “4”, 5 and “6” should appear as subscripts.
- In claim 90, there is a peptide that is designated as SEQ ID NO: 99. The sequence that is recited in the claim shows lysine as the C-terminal amino acid. However, in SEQ ID NO: 99 of the sequence listing, the C-terminal amino acid is glutamic acid, not lysine.
- Claim 101 recites the following: “from about 4 to 10”.

Use of the term “about” in this way renders the upper and lower limits of the claim indefinite. Another layer of indefiniteness exists as well, since claim 83 imposes a strict lower limit of 4 on the value of “n”, whereas claim 101 would permit “n” to be 3, or even less. Accordingly, the claim dependence is improper. However, even if claim 101 were to be written in independent form, the rejection would be maintained, since use of the term “about” in this way renders the upper and lower limits of the claim indefinite. The same issues apply in the case of claim 102.



The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 83 is rejected under 35 U.S.C. §102(e) as being anticipated by Kemp (USP 5,688,760).

Kemp discloses a peptide in figure 1. As is evident, the subsequence TRSAW occurs at residues 107-111, and (Lys)<sub>4</sub> occurs at residues 147-150. [The sequence TRSAW corresponds to SEQ ID NO: 53 of the instant application].

The issue here concerns the term "having". Claim 83 does not recite that "Z" consists of (Lys)<sub>4-10</sub>, but rather that "Z" is a peptide "having" the sequence (Lys)<sub>4-10</sub>. Accordingly, one can add any number of amino acids to the N-terminus of "Z" before bonding to "X".

Thus, the claim is anticipated.



No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in cursive script, appearing to read 'David Lukton'.

DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800